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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,477	12/11/2003	David C. Hovda	S-16	2479

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EXAMINER	
TOY, ALEX B	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,477	HOVDA, DAVID C.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,10,11,13-23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,10,11,13-23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on March 28, 2006. The objections to the drawings and claims 9 and 14 are withdrawn in view of the canceled claims or appropriate amendments. The 35 U.S.C. 112, first paragraph rejections are withdrawn. It is noted, however, that based on applicant's remarks, a viewing means is all the structure that is necessary to measure a void or the shrinkage of tissue.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4-5, 10-11, 13-18, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Underwood et al. (U.S. Pat. No. 6,277,112 B1).

Regarding claim 1, Underwood et al. disclose a method for treating an intervertebral disc comprising:

Advancing at least one optic fiber 324 into a nucleus of the disc through an access device 302 (col. 26, ln. 53-59, col. 27, ln. 2-3 and 6-8, and Figs. 16 and 17); and

Viewing an interior of the disc using at least one of the optic fibers (Figs. 17 and 18).

Regarding claim 2, Underwood et al. disclose the method of claim 1, further comprising advancing an access device into the disc to create a passageway into the disc with the access device (col. 27, ln. 44-49).

Regarding claim 4, Underwood et al. disclose the method of claims 1 and 2, further comprising:

Advancing a treatment device 310 through the access device 302 (Fig. 16); and

Activating the treatment device to treat the disc (col. 27, ln. 64 – col. 28, ln. 16 and Fig. 18).

Regarding claim 5, Underwood et al. disclose the method of claims 1, 2, and 4, wherein activating the treatment device occurs prior to viewing the interior of the disc (Fig. 18). Since the treatment device of Underwood et al. must first remove tissue from the interior of the disc in order for the optical fiber to be able to view the interior, the treatment device is inherently activated prior to viewing the interior of the disc.

Regarding claim 10, Underwood et al. disclose the method of claims 1, 2, and 4, wherein the treatment device includes at least one active electrode 357 and a return electrode 350, wherein activating the treatment device comprises applying a high frequency voltage between the active and return electrodes (col. 27, ln. 64-67 and Fig. 17).

Regarding claim 11, Underwood et al. disclose the method of claims 1-2, 4, and 10, further comprising using a conductive medium to form a current path between the active and return electrodes (col. 27, ln. 40-42 and 53-58 and Fig. 17)

Regarding claim 13, Underwood et al. disclose the method of claims 1-2, 4, and 10-11, where the conductive medium is the naturally occurring fluid within the disc. The naturally occurring fluid is inherently present in the disc. Therefore, the conductive medium must inherently comprise at least the naturally occurring fluid.

Regarding claim 14, Underwood et al. disclose the method of claims 1, 2, (and 4) wherein advancing the treatment device comprises advancing the treatment device into a nucleus pulposus of the disc (col. 27, ln. 44-49).

Regarding claim 15, Underwood et al. disclose the method of claims 1, 2, and 4, wherein activating the treatment device comprises ablating tissue within the disc (col. 27, ln. 64-67 and Figs. 17 and 18).

Regarding claim 16, Underwood et al. disclose the method of claims 1-2, 4, and 15, further comprising observing the effect of the ablating of tissue using the optic fiber (col. 28, ln. 17-18).

Regarding claim 17, Underwood et al. disclose the method of claims 1-2, 4, and 15-16, wherein observing the effect comprises measuring a void created by the ablating of tissue (col. 28, ln. 22-23).

Regarding claim 18, Underwood et al. disclose the method of claims 1-2, 4, and 15-16, wherein observing the effect comprises observing an outer portion of the disc. The device of Underwood et al. is inherently capable of observing an outer portion of the disc when observing the effect of ablation (Fig. 18).

Regarding claim 25, Underwood et al. disclose the method of claim 1, where advancing the at least one optic fiber into the nucleus of the disc via the access device is performed during an open surgical procedure (col. 3, ln. 27-33).

Regarding claim 26, Underwood et al. disclose the method of claim 1, where advancing the at least one optic fiber into the nucleus of the disc via the access device is performed during a percutaneous surgical procedure (col. 4, ln. 46-50).

Claims 1-2, 4, 19-20, and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by another embodiment of Underwood et al.

Regarding claim 1, in another embodiment Underwood et al. disclose a method for treating an intervertebral disc comprising:

Advancing at least one optic fiber 280 into a nucleus of the disc through an access device 278 (col. 24, ln. 12-17 and Fig. 13); and

Viewing an interior of the disc using at least one of the optic fibers (Figs. 13-15).

Regarding claim 2, in another embodiment Underwood et al. disclose the method of claim 1, further comprising advancing an access device into the disc to create a passageway into the disc with the access device (col. 24, ln. 30-35).

Regarding claim 4, in another embodiment Underwood et al. disclose the method of claims 1 and 2, further comprising:

Advancing a treatment device 284 through the access device 278 (Figs. 13-15); and

Activating the treatment device to treat the disc (col. 25, ln. 35-38).

Regarding claim 19, in another embodiment Underwood et al. disclose the method of claims 1, 2, and 4, wherein activating the treatment device comprises coagulating tissue within the disc (col. 3, ln. 48-53). It is noted that causing tissue to shrink constitutes coagulating tissue as evidenced by claim 21.

Regarding claim 20, in another embodiment Underwood et al. disclose the method of claims 1-2, 4, and 19, further comprising observing the effect of the coagulating of tissue using the optic fiber (Fig. 14).

Regarding claim 22, in another embodiment Underwood et al. disclose the method of claims 1-2, 4, and 19-20, wherein observing the effect comprises observing an outer portion of the disc. The device of Underwood et al. is inherently capable of observing an outer portion of the disc when observing the effect (Fig. 15).

Regarding claim 23, in another embodiment Underwood et al. disclose the method of claims 1, 2, and 4, further comprising performing non-invasive imaging prior to or during activating the treatment device (col. 24, ln. 1-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 7-8, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Underwood et al.

Regarding claim 3, Underwood et al. disclose the method of claims 1 and 2. The claim differs from Underwood et al. in calling for advancing the access device into the disc to comprise separating layers of a fibrous outer portion of the disc to create a passageway into the disc with the access device. Underwood et al., however, disclose another embodiment of their invention in which the access device 702 comprises a needle (as called for by the applicant on page 17, ¶ 70 of the specification) that advances into the disc to separate layers of a fibrous outer portion of the disc to create a passageway into the disc that causes less damage and is re-sealable. (col. 33, ln. 25-

34, col. 33, ln. 45-55, and Figs. 34-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of advancing the access device of Underwood et al. comprise separating layers of a fibrous outer portion of the disc to create a passageway into the disc with the access device in view of another embodiment of Underwood et al. to create a passageway that causes less damage and is re-sealable.

Regarding claim 7, Underwood et al. disclose the method of claims 1, 2, and 4. The claim differs from Underwood et al. in calling for advancing of the at least one optic fiber and viewing the interior of the disc to be performed intermittently through said method. In view of the method disclosed by Underwood et al., however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have intermittently advanced at least one optic fiber and viewed the interior of the disc because the user would obviously remove tissue and intermittently advance at least one optic fiber and view the interior of the disc to see how much tissue had been removed.

Regarding claim 8, Underwood et al. disclose the method of claims 1 and 2. The claim differs from Underwood et al. in calling for advancing the access device to comprise inserting a needle into at least a fibrous outer portion of the disc. Underwood et al., however, disclose another embodiment of their invention in which the access device 702 comprises a needle (as called for by the applicant on page 17, ¶ 70 of the specification) that is inserted into a fibrous outer portion of the disc to create a passageway into the disc that causes less damage and is re-sealable. (col. 33, ln. 25-34, col. 33, ln. 45-55, and Figs. 34-36). Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to have the method of advancing the access device of Underwood et al. comprise inserting a needle into at least a fibrous outer portion of the disc in view of another embodiment of Underwood et al. to create a passageway that causes less damage and is re-sealable.

Regarding claim 21, in another embodiment Underwood et al. disclose the method of claims 1-2, 4, and 19-20. The claim differs from another embodiment of Underwood et al. in calling for observing the effect to comprise measuring shrinkage of tissue resulting from the coagulation of tissue. In one embodiment Underwood et al., however, teach measuring a void created by the ablating of tissue (col. 28, ln. 22-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the method of observing of Underwood et al. comprise measuring shrinkage of tissue resulting from the coagulation of tissue in view of one embodiment of Underwood et al. because it is obvious to use the same method to measure a void to monitor treatment progress, whether the void is created by coagulation or ablation.

Response to Arguments

Applicant's arguments filed on March 28, 2006 have been fully considered but they are not persuasive.

Applicant argues that Underwood does not disclose inserting a fiber optic into the nucleus of the disc and viewing the interior of the disc as specified in claim 1. As cited by the examiner in the previous Action, Fig. 17 clearly shows the electrode distal end

probe and the endoscopic lens 324 attached to an eyepiece for viewing (col. 27, ln. 1-8). This structure is clearly the same structure that is shown in Fig. 18 (see col. 26, ln. 53 – col. 28, ln. 23). Thus, Figure 18 shows the portion of the instrument with the lens 324 inside the nucleus 372 and clearly viewing the interior of the disc as nucleus tissue is ablated away. To add further support, Underwood discloses that: "After the desired volume of nucleus pulposis is removed (based on direct observation through port 324 ...), instrument 310 is withdrawn ..." (col. 28, ln. 17-20).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT AT
6/1/06

MICHAEL PEFFLEY
PRIMARY EXAMINER